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Are Foot Orthoses Effective at Reducing Pain in Adults with Foot Osteoarthritis?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not "Are foot orthoses effective at reducing pain in adults with foot osteoarthritis?"

STUDY DESIGN: A review of two randomized controlled trials and one case series from peer-reviewed journals published between 2010 and 2016.

DATA SOURCES: Two randomized controlled trials and one case series were found using PubMed.

OUTCOME MEASURED: Reduction of the subject's foot pain was the patient-oriented outcome measured in each of these three articles. The subject's pain was scored on a Likert scale and evaluated at baseline and at 12 weeks to assess their response to foot orthoses.

RESULTS: The first randomized controlled trial analyzed determined that prefabricated foot orthoses improved subject Foot Health Status Questionnaire (FHSQ) pain domain scores similar to rocker-sole footwear in patients with 1st metatarsophalangeal joint osteoarthritis (Menz HB, Auhl M, Tan JM, Levinger P, Roddy E, Munteanu SE. *Arthritis Care Res*. 2016;68(5):581-589. doi: 10.1002/acr.22750 [doi]). A case series determined that custom-made semi-rigid foot orthoses with or without carbon fiber foot plates reduced average pain scores in patients with midfoot osteoarthritis (Ibuki A, Cornoiu A, Clarke A, et al. *Prosthet Orthot Int*. 2010;34(4):461-471. doi: 10.3109/03093646.2010.503672.). The final randomized controlled trial examined found that functional foot orthoses (FFO) did reduce subject "average pain in the month" questionnaire scores similar to sham orthoses in adults with midfoot osteoarthritis. However, the study had a wide estimate of treatment effect making it difficult to determine if there was a difference between interventions (Chapman GJ, Halstead J, Redmond AC. *Gait Posture*. 2016;49:235-240. doi: 10.1016/j.gaitpost.2016.07.012.).

CONCLUSIONS: The two randomized controlled trials and one case series in this review showed some data to suggest foot orthoses are effective at reducing pain in adults with foot osteoarthritis. However, future randomized controlled trials are needed to determine if foot orthoses are superior to other treatment options for foot osteoarthritis.

KEY WORDS: foot orthoses, osteoarthritis

INTRODUCTION

Osteoarthritis (OA) is the most common type of arthritis, where all structures of the joint have undergone pathologic change leading to joint failure. OA commonly affects the cervical and lumbosacral spine, proximal and distal interphalangeal joints of the hands, carpometacarpal joint of the thumb, as well as joints of the hip, knee, and feet.[1] Within the foot, the first metatarsophalangeal (MTP) joint is most commonly affected, followed by the second cuneometatarsal and talonavicular joints.[2]

It is estimated 22.7% (54.4 million) of adults in the United States have doctor diagnosed arthritis, with significantly higher age-adjusted prevalence in women (23.5%) than in men (18.1%).[3] About 43.5% (23.7 million) of 54.4 million adults with doctor-diagnosed arthritis have limitations in their usual activities due to their arthritis.[3] As the US population continues to age, the prevalence of doctor-diagnosed arthritis is expected to increase. By the year 2040, an estimated 78.4 million adults aged 18 years and older will have doctor-diagnosed arthritis.[3] Foot pain affects one in four people aged over 75 years, two-thirds of whom have related locomotor disability.[2] Symptomatic foot OA affects 17% of adults aged 50 years and over.[2]

In 2013, total medical care expenditures attributed to arthritis and earning losses were 303.5 billion, or 1% of the 2013 US gross domestic product.[4] In that year, OA accounted for $16.5 billion (4.3%) of the combined costs for all hospitalizations, second to septicemia.[5] OA was the leading cause (46%) of hospitalizations among all arthritis diagnoses and was diagnosed in 23.7 million healthcare visits in 2013.[6] Nearly 3 million hospital stays in 2013 had an OA diagnosis.[6]

OA is a disease caused by hyaline articular cartilage loss, which is accompanied by increasing thickness and sclerosis of the subchondral bony plate, outgrowth of osteophytes at the

joint margin, stretching of the articular capsule, variable degrees of synovitis, and weakness of muscles bridging the joint.[1] Joint vulnerability and joint loading are the two major factors contributing to the development of OA, with the cartilage being the primary target tissue for disease.[1]

Patients with OA experience a slow onset of pain affecting one or a few joints at a time that is increased with joint use and relieved with rest.[7] Joint stiffness is short lived (<30 minutes) and is early morning or inactivity related.[7] Other features include mild swelling and absence of constitutional symptoms.[7] Signs of OA include: swelling, deformity, muscle wasting, joint line tenderness, crepitus, and reduced range of motion.[7] First MTP joint OA is usually bilateral, and when symptomatic leads to localized big toe pain on standing and during ambulation.[7] Bony enlargement of the first MTP joint, hallux valgus, hallux rigidus, and cross-over toes are common deformities, frequently leading to the development of a complicating bursa with additional fibrous tissue reactions on the medial aspect of the first MTP joint.[7]

Management of foot OA generally begins with conservative interventions, including analgesic or anti-inflammatory medications, intra-articular injections, physical therapy, footwear modifications, foot orthoses, and surgery.[2,8]

There is currently no cure for foot OA and there are few randomized controlled trials demonstrating efficacy of one treatment vs. another. Foot orthoses may show to be an effective intervention for reducing pain in adults with foot osteoarthritis.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not "Are foot orthoses effective at reducing pain in adults with foot osteoarthritis?"

METHODS

Three studies on the use of foot orthoses as treatment for foot osteoarthritis in adults were selected for analysis. Menz et al. compared prefabricated foot orthoses vs. rocker-sole footwear in adults with 1st MTP OA, Ibuki et al. compared custom-made semi-rigid foot orthoses with or without carbon fiber foot plates in patients with midfoot OA, and Chapman et al. compared functional foot orthoses (FFO) vs. sham foot orthoses in adults with midfoot OA. Each study looked at the outcome of subject pain reduction.

Data sources were searched using key words "foot orthoses" and "osteoarthritis". All articles were published in English and in peer-reviewed journals. Articles were searched via PubMed and selected based on their relevance to the clinical question and that the outcome of the study mattered to the patient (POEM). Articles were included if they were clinical studies and randomized controlled trials published after 2008 on human subjects, in English language. Clinical studies and randomized controlled trials published in 2008 or earlier on non-human subjects, in non-English language were excluded. Statistics used and reported include: mean change from baseline, p-value, confidence interval (CI), relative risk (RR), and number needed to harm (NNH). Menz et al. and Chapman et al. are both randomized controlled trials, while Ibuki et al. is a case series. Table 1 illustrates the various characteristics of the studies analyzed during this selective EBM review.

Table 1. Demographics and characteristics of included studies.[8-10]

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Intervention
Menz[8] (2016)	RCT	102	Orthoses Group 57.1 ± 11.1 years old Footwear Group 56.5 ± 11.1 years old	Age ≥ 18 years, report 1st MTP joint: pain for at least 12 weeks, <64°of dorsiflexion ROM, TTP of the dorsal aspect of the joint. Be able to walk >50 meters without assistance, abstain from additional interventions (PT, other orthoses, shoe modification, injections, or surgery) and d/c pain medication 14 days prior to and for the duration of the study.	Pregnancy, previous 1st MTP joint surgery, significant 1st MTP deformity, or intraarticular injection (in the past 6 mo) of the 1st MTP joint. Presence of other foot or ankle condition, systemic inflammatory condition, connective tissue disease, cognitive impairment, or hx of recurrent falls (≥ 2 in the last year), currently wearing contoured foot orthoses, specialized footwear or footwear that would not accommodate foot orthoses.	Orthoses Group – 5 Footwear Group – 5 Total - 10	Prefabricated foot orthoses vs. rocker-sole footwear
Ibuki [9] (2010)	Case Series	57	Range – 37-81 years old Mean – 63.95 years old	Dx of midfoot OA with radiographic evidence, midfoot pain	Presence of other symptomatic conditions of feet or ankles unrelated to midfoot OA, previously received the same orthotic tx as prescribed in the study	0	Foot orthoses with and without rigid carbon fiber foot plates
Chapman[10] (2016)	RCT	37	Mean – 58.4 years old	Age ≥ 18 years, Dx of midfoot OA with radiographic evidence, midfoot pain ≥ 3 months	Hx of inflammatory joint disease, neuropathy, or stress fractures, LE surgery in the last year, existing use of OTC or Rx foot orthoses	4	Functional foot orthoses vs. sham foot orthoses

OUTCOME MEASURED

Reduction of the subject's foot pain was the patient-oriented outcome measured in each of these three articles. The subject's pain was scored on a Likert scale and evaluated at baseline and at 12 weeks to assess their response to foot orthoses.

In the study conducted by Menz et al., the outcome measured was the subject's foot pain domain of the Foot Health Status Questionnaire (FHSQ), which is a foot specific, health related quality of life outcome measure.[8] Questions within each domain are scored ranging from 0 indicating very poor foot health to 100 indicating optimum foot health.[8] Ibuki et al. developed patient evaluation questionnaires where patients rated their average level of pain, from 0 indicating 'no pain' to 10 indicating 'worst pain'.[9] Chapman et al. assessed subject's average pain in the last month using an 11-point numeric rating scale scored from 'no pain' to 'pain as bad as you can imagine'.[10]

RESULTS

This selective EBM review utilized two randomized controlled trials and one case series to determine the efficacy of foot orthoses at reducing pain in adults with foot osteoarthritis. All three studies took place in outpatient settings.[8-10]

The first study conducted by Menz et al. was a parallel-group randomized controlled trial comparing prefabricated foot orthoses vs. commercially available rocker-sole footwear for the treatment of 1st MTP OA.[8] Participants were recruited via radio, newspaper, and social media advertisements.[8] To be included in the study, participants must be: ≥ 18 years of age, report 1st MTP joint pain for at least 12 weeks, have <64°of dorsiflexion ROM of the 1st MTP joint, have pain with palpation to the dorsal aspect of the 1st MTP joint, be able to walk >50 meters without assistance, abstain from additional interventions (PT, other orthoses, shoe modification,

injections, or surgery) during the study and willingly discontinue pain medication 14 days prior to and for the duration of the study.[8] Participants were excluded if they were pregnant, had previous 1st MTP joint surgery, significant 1st MTP deformity, or had intraarticular injection (in the past 6 mo) of the 1st MTP joint.[8] Researchers also excluded participants if they were diagnosed with another foot or ankle condition, a systemic inflammatory conditions, a connective tissue disease, cognitive impairment, had history of recurrent falls (≥ 2 in the last year), currently wearing contoured foot orthoses, specialized footwear or footwear that would not accommodate foot orthoses.[8] Of the 326 assessed for eligibility, 102 participants were randomized using permuted block randomization to either the prefabricated foot orthoses group (n = 52) or the rocker-sole footwear group (n = 50).[8] In the foot orthoses group, one participant withdrew as they could not tolerate the orthoses and four were lost to follow-up giving a completion rate of 90%.[8] In the rocker-sole footwear group, four withdrew consent after randomization leaving forty-six participants who received the allocated intervention.[8] Of these subjects, three were lost to follow up and two could not tolerate the footwear giving a completion rate of 89%.[8] The primary outcome measure was the foot pain domain of FHSQ measured at baseline, 4, 8, and 12 weeks.[8] In order to compare this RCT to other studies, this review focuses on subject FHSQ pain domain score at baseline and 12 weeks. Table 2 illustrates improvement in subject baseline mean score to 12-week follow up in both the functional foot orthoses group and rocker-sole footwear group. A p-value of 0.477 indicates there is no significant difference between the two groups.[8]

Table 2. Subject FHSQ pain domain (0-100) score in Menz et al.[8]

	Orthoses Group (n = 52)	**Rocker-Sole Footwear Group (n = 46)**
Baseline Mean ± (SD)	56.7 ± (19.2)	51.5 ± (20.3)
12 weeks Mean ± (SD)	73.6 ± (16.8)	73.7 ± (14.8)
Mean change from baseline (Calculated)	16.9	22.2
P-value	0.477	

Table 3 demonstrates the most commonly reported adverse events during the Menz et al. study. Participants in the rocker-sole footwear group were more likely to report new onset low back pain during the study than the functional foot orthoses group.[8] A p-value of 0.048 indicates statistically significant difference between the two interventions. Researchers calculated NNH is 8 (3.9, 71.0) with 95% CI meaning that for every eight patients treated with rocker-sole footwear, one more patient would experience low back pain than if they were treated with functional foot orthoses.[8] Adherence varied markedly between the two groups. Researchers found that the footwear group wore their shoes for an average of 287 hours in total throughout the 12-week study period compared to the 448 hours for the orthoses group.[8]

Table 3. Adverse events reported during Menz et al. study.[8]

Adverse Event Number (%)	**Orthoses Group (n = 52)**	**Rocker-Sole Footwear Group (n = 46)**	**Relative Risk (95% CI)**	**P Value**	**NNH (95% CI)**
New Low Back Pain	2 (3.8)	8 (17.4)	4.52 (1.01, 20.22)	0.048	8 (3.9, 71.0)
Experienced Fall	5 (11.1)	4 (10.3)	0.92 (0.27, 3.20)	0.900	
Blisters	2 (3.8)	3 (6.5)	1.34 (0.45, 4.00)	0.442	
Discomfort	2 (3.8)	3 (6.5)	1.34 (0.45, 4.00)	0.442	

Ibuki et al. conducted a case series to determine the effects of custom-made semi-rigid foot orthoses alone and with rigid carbon fiber footplates on adults with midfoot OA.[9] Subjects were recruited through a private orthopedic foot and ankle clinic and were assessed by an orthopedic surgeon.[9] Subjects met inclusion criteria if they had a diagnosis of unilateral or bilateral midfoot OA with radiographic evidence or had the presence of pain in the midfoot region.[9] Subjects were excluded if they had any other symptomatic conditions of their feet or ankles unrelated to midfoot OA or if they previously received the same orthopedic treatment as prescribed in this study, i.e. semi-rigid foot orthoses or carbon fiber footplates.[9] A total of 57 subjects were included for analysis.[9] All were fitted with custom-made semi-rigid foot orthoses and 36 (63%) also had carbon fiber footplates modified into their footwear.[9] Subjects were given pre-treatment, 6-week, 12-week, and 24-week patient evaluation questionnaires.[9] In order to compare to other studies, this review focuses on the 'average level of pain' component of the questionnaire pre-treatment and at 12 weeks. Table 4 shows a 1.61 mean reduction of the patient's baseline average pain. Researchers calculated a p-value of <0.01, which indicates a statistically significant change from baseline.[9] Researchers did not separate the data into foot orthoses alone vs. foot orthoses and carbon fiber foot plates and stated a RCT would be necessary to determine if the use of carbon fiber foot palates has any additional benefit to foot orthoses alone.[9] Ibuki et al. also did not mention any analysis compliance, tolerability or adverse events.

Table 4. Subject's "average level of pain" (0-10) score in Ibuki et al.[9]

Baseline Mean ± (SD)	4.70 ± (1.63)
12 weeks Mean ± (SD)	3.09 **±** (1.85)
Mean change from baseline (Calculated)	-1.61
P-value	<0.01

Chapman et al. conducted a double blind, two arm parallel group randomized controlled trial to determine the effects of functional foot orthoses vs. sham control orthoses in adults with midfoot OA.[10] Participants were recruited at an outpatient clinic and included if they were ≥ 18 years of age, had diagnosed midfoot OA with radiographic evidence, or experienced midfoot pain for ≥ 3 months.[10] Subjects were excluded if they had a history of inflammatory joint disease, neuropathy, stress fractures, lower limb surgery in the last year, or had existing use of OTC or prescription foot orthoses.[10] A total of 37 participants were randomized into the functional foot orthoses group (n= 19) and sham orthoses control group (n=18).[10] A total of 4 patients did not complete the study giving an attrition rate of 11%.[10] One discontinued the functional foot orthoses due to pain related to the intervention.[10] In the control group, one was lost to follow up and two discontinued intervention due to pain unrelated to the sham orthoses.[10] Chapman et al. assessed subject's average pain in the last month using an 11-point numeric rating scale scored from 'no pain' to 'pain as bad as you can imagine' at baseline and 12 weeks.[10] Table 5 illustrates a mean change from baseline of patient's "pain on average in last month" in both the functional foot orthoses group (-1.6 ± 2.0) and the sham orthoses group (-1.2 ± 1.1).[10] Researchers calculated a mean difference of functional foot orthoses to sham orthoses is -0.4 (95% CI -1.6-0.8) indicating a wide estimate of treatment effect making it difficult to determine the efficacy of both interventions. Chapman et al. also did not mention any analysis compliance, tolerability or adverse events during this RCT.[10]

Table 5. Subject's "pain on average in last month" (0-11) score in Chapman et al.[10]

	Functional Foot Orthoses (FFO) Group n = 19	**Sham Orthoses Group n = 18**
Baseline Mean ± (SD)	6.0 ± (1.6)	6.0 ± (1.9)
12 weeks Mean ± (SD)	4.3 ± (1.9)	4.5 ± (1.9)
Mean change from baseline ± (SD)	-1.6 ± (2.0)	-1.2 ± (1.1)
Mean difference of FFO-sham (95% CI)	-0.4 ± (-1.6 to 0.8)	

DISCUSSION

Foot orthoses are commonly available in the United States, but the cost depends on several factors such as if the orthoses are over the counter (OTC), non-prescription orthoses made custom by do-it-yourself foot molds, or if a doctor prescribes them. Even when prescribed, depending on the patient's health insurance, foot orthoses are sometimes excluded from coverage. According to CostHelper Health Incorporated, an online price quoting company, OTC foot orthoses cost about $10-$80, about $100-$200 for non-prescription orthotics, and about $200-$800 for prescription custom orthotics for uninsured patients and patients not covered by health insurance.[11]

In terms of limitations of this review, when searching for randomized controlled trials studying efficacy of foot orthoses for foot osteoarthritis, results were scarce. The study conducted by Menz et al. was the first RCT to evaluate the effectiveness of mechanical interventions in reducing foot pain in people with first MTP joint OA.[8]

In the study conducted by Menz et al., both interventions improved FHSQ pain scores. Researchers thought it possible that the rocker-sole shoes have a potential for greater effectiveness if barriers to adherence could be overcome.[8] Since the orthoses group had higher

adherence and lower rates of adverse events, researchers thought it may be the preferred intervention.[8] One major limitation of the study was that subjects were not blinded to the intervention. Since subjects were recruited via radio, newspaper, and social media advertisements and volunteered for the study, selection bias was introduced. As a result, generalizability of the study is questionable.

In the case series conducted by Ibuki et al., researchers discussed that subjects who received carbon fiber footplates in addition to functional orthoses did not seem to experience greater relief than those who only received the functional orthoses, but a randomized controlled trial would be needed to determine if the carbon fiber footplate has any additional benefits.[9] A major limitation of the Ibuki et al. case series was the lack of a control group. Researchers also commented on the reliability and validity of the questionnaires utilized.[9]

In the randomized controlled trial conducted by Chapmen et al., researchers recognized that future studies with more objective and sensitives measures should be utilized to detect impairment and pain related function instead of subjective pain questionnaires.[10] Researchers also noted that they would recommend a trial including a third, active monitoring arm with no planned treatment in order to better understand placebo effect.[10]

CONCLUSIONS

The two randomized controlled trials and one case series in this review showed some data to suggest foot orthoses are effective at reducing pain in adults with foot osteoarthritis. However, future randomized controlled trials are needed to determine if foot orthoses are superior to other treatment options for foot OA. Though sample size and duration of treatment was sufficient for the three studies in this review, randomized controlled trials with larger sample sizes, longer duration, and third control arm with no planned treatment would benefit future studies.

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